Full Text HD-97-006

PREVENTION OF OSTEOPOROSIS

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National Institute of Child Health and Human Development
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Application Receipt Date: September 5, 1997

PURPOSE

The National Institute of Child Health and Human Development (NICHD) and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invite studies of strategies to prevent osteoporosis. The purpose of this Request for Applications (RFA) is to develop methods to prevent osteoporosis by physical activity and dietary means in childhood.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Prevention of Osteoporosis, is related to the priority areas of nutrition and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Racial/ethnic from minority individuals, persons with disabilities, and women are encouraged to apply as Principal Investigators.

MECHANISM OF SUPPORT

The mechanisms available for support of applications in response to this RFA will be through the National Institutes of Health (NIH) Research Project Grant (R01) and FIRST Award (R29) programs. Policies that govern the grants award programs of the PHS will prevail. The support of grants pursuant to the RFA is contingent upon receipt of appropriated funds for this purpose.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and will be reviewed by a Division of Research Grants (DRG) study section. However, if it is determined that there is a sufficient continuing program need, the sponsoring Institutes may announce a request for competitive continuation applications. The total project period for applications submitted in response to this RFA may not exceed four years. A maximum of three years may be requested for foreign awards. The earliest anticipated award date is April 1, 1998.

FUNDS AVAILABLE

It is anticipated that four to six new grants will be awarded under this program, contingent upon receipt of a sufficient number of meritorious applications and the availability of funds. The NICHD and NIAMS have set aside $1.4 million for total costs in the first year.

RESEARCH OBJECTIVES

Background

Osteoporosis afflicts an estimated 25 million Americans and generates annual medical costs of about $13.8 billion. Osteoporotic fractures result in substantial morbidity and mortality, but a significant portion of the economic and human costs can be averted through efforts at prevention.

Peak bone mass is a major determinant of fracture risk in later life. Although genetic factors control most of skeletal development, up to 20% of bone mass is regulated by controllable factors such as nutrition and exercise. Since approximately 40% of the adult bone mineral content is accumulated during adolescence, this is an extremely important time to focus on practices that optimize skeletal health.

Although it is known that calcium and other nutrients in dairy products contribute to the development of a healthy skeleton, results of the USDA Household Survey and the NHANES III indicate that the average adolescent girl consumes only about 800 mg of calcium per day, which is 400 mg less than the current recommended daily allowance and 700 mg less than the amount recommended by the NIH Consensus Conference on Optimal Calcium Intake in June 1994. Moreover, a comparison between NHANES II (1976-80) and NHANES III (1988-91) indicates a decline of about 100 milligrams in daily calcium intake in male and female children 6-to-11 years old.

Results of the Teen Lifestyle Project showed that two-thirds of adolescent girls are dieting and that 90% of white girls are dissatisfied with their body image. Their concerns about body weight lead them to substitute low-calorie drinks for dairy products in their diet. When carried to extremes, dieting among adolescent girls can lead to anorexia, amenorrhea, and osteopenia, a triad seen in high performance athletes and dancers. Although osteoporosis is more common in women, about one-fifth of osteoporotic fractures occur in men; and, occasionally men suffer from severe osteoporosis in middle age. Therefore, studies of the antecedents of osteoporosis should not be limited to females.

Studies of calcium supplementation have indicated that a significant increase in bone mineral density can be demonstrated in children and adolescents given supplemental calcium. It appears as if there may be a narrow window of time during which calcium supplementation will engender an increase in bone density. In the setting of the prevailing high-sodium, low-magnesium diet in the United States, it also appears as if augmented calcium intake may be necessary to maintain any increase in bone density attained during adolescence.

Research Scope

The objective of this RFA is to encourage and promote new and innovative research to prevent the development of osteopenia and osteoporosis by focusing on strategies applicable during childhood and adolescence. The following are examples of research topics that are appropriate for this RFA; however, they are not to be considered as exclusive or limiting:

o Studies focused on calcium, magnesium, and sodium intake in children and adolescents; the public health implications of preventing osteoporosis; education and motivational research; and exercise as a preventive measure.

o Identifying children at high risk of developing osteoporosis later in life. Intervention could then be directed at especially vulnerable children rather than attempting to increase calcium consumption among all adolescents. Intervention studies – especially those testing alterations in calcium, sodium, magnesium, and vitamin intake - are encouraged that target children and adolescents found to be at high risk for osteoporosis later in life.

o Exploring relationships between physical activity and bone mineral acquisition and between bone mineral content and bone strength during childhood and adolescence.

o Elucidating genetic, physical, biochemical, and dietary markers to identify those children and adolescents at highest risk of osteoporosis later in life; and/or intervention studies of nutrition and/or exercise in preventing osteopenia and osteoporosis.

o Elucidating the interplay of genetic, hormonal, and environmental factors influencing the assimilation of dietary calcium, the renal excretion of calcium, and the incorporation of calcium into bone. In this regard the body's capacity to adapt to low dietary intake of calcium is of particular interest; as are studies that address the importance of ratios of minerals in the diet in this regard, e.g., calcium:magnesium and calcium:sodium.

o Either animal trials or clinical studies may be submitted in response to this RFA, but the limited funds available preclude funding of any large-scale clinical trials.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 5/95) is to be used in applying for these grants. Applications kits are available at most institutional offices of sponsored research and may be obtained from the Office of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, E-mail: asknih@odrockm1.od.nih.gov.

The RFA label available in the application form PHS 398 (rev. 5/95) must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title (PREVENTION OF OSTEOPOROSIS) and number (HD-97-006) must be typed on line 2 of the face page of the application and the YES box must be checked.

FIRST (R29) award applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST (R29) award applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, exact photocopies, in one package to:

DIVISION OF RESEARCH GRANTS
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, SUITE 1040, MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must also be sent to:

Susan Streufert, Ph.D.
Division of Scientific Review

National Institute of Child Health and Human Development 6100
Executive Boulevard, Room 5E01 - MSC 7510
Bethesda, MD 20892-7510

Applications prepared in response to this RFA must be received by September 5, 1997. If an application is received after that date, it will be returned to the applicant without review. The Division of Research Grants (DRG) will not accept any application in response to this RFA that is essentially the same as one pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such must applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by the NICHD. Incomplete or non-responsive applications will be returned to the applicant without further consideration. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NICHD in accordance with the review criteria stated below. As part of the initial merit review, a process may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA. Applications judged to be competitive will be discussed in depth and assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration. A summary statement will be prepared, and the principal investigator and the official signing for the applicant organization will be notified.

Review Criteria

The review criteria for the evaluation of applications are:

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Investigator: is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?~

The initial review group will also examine: the adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research and plans for the recruitment and retention of subjects; the provisions for the protection of human and animal subjects; and the safety of the research environment.

AWARD CRITERIA

Scientific merit and technical proficiency, as determined by peer review, based on the demonstrated and projected capabilities described in the application, will be the predominant criteria for determining funding priorities.

Schedule

Application Receipt Date: September 5, 1997
Review by Advisory Council: January 1998
Anticipated Date of Award: April 1, 1998

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged.

The opportunity to clarify any issues or questions from potential applicants is welcomed.

Direct inquiries regarding programmatic issues to:

Gilman D. Grave, M.D.
Center for Research for Mothers and Children
National Institute of Child Health and Human Development 6100
Executive Boulevard, Room 4B11 - MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 496-5593
FAX: (301) 480-9791
Email: GRAVEG@HD01.NICHD.NIH.GOV

Joan A. McGowan, Ph.D.
Bone Diseases Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building, Room 5AS-43E
45 Center Drive, MSC 4500
Bethesda, MD 20892-6500
Telephone: (301) 594-5055
FAX: (301) 480-4543
Email: joan_mcgowan@nih.gov

Direct inquiries regarding fiscal matters to:

E. Douglas Shawver
Grants Management Branch
National Institute of Child Health and Human Development 6100
Executive Boulevard, Room 8A17 - MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 496-1303
FAX: (301) 402-0915
Email: SHAWVERD@HD01.NIH.GOV

Vicki Maurer
Grants Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Natcher Building, Room 5AS-49A
45 Center Drive, MSC 4500
Bethesda, MD 20892-6500
Telephone: (301) 594-3504
FAX: (301) 480-4543
Email: vicki_maurer@nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.865, Research for Mothers and Children and Catalog of Federal Domestic Assistance No. 93.846, Arthritis, Musculoskeletal and Skin Research. Awards are made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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